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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/501,892

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Shigeru Hiramoto

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EXAMINER

MI, QIUWEN

ART UNIT

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1655

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/501,892	Applicant(s) HIRAMOTO ET AL.	
	Examiner Qiuwen Mi	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicant's amendment in the reply filed on 9/14/07 is acknowledged. Any rejection that is not reiterated is hereby withdrawn.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/18/2007 has been entered.

Claims Pending

Claims 22-24 are new added. Claims 1-14 are cancelled. Claims 15-24 are pending. Claims 15-24 are examined on the merits.

Claim Rejection 112, 1st

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

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art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a method for inhibiting *Helicobacter pylori* adhesion or treating disease associated with *Helicobacter pylori* comprising administering to a subject an effective amount of a product of browning reaction.

To provide adequate written description and evidence of possession of a claimed invention, the specification must provide sufficient distinguishing identifying characteristics of the invention. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In the instant case, the invention only provides the description of browning reaction products made from casein & lactose, caseinate & lactose, lactoglobulin & lactose, lactalbumin & lactose, skim milk, whey, caseinate & glucose, caseinate & lactose, soybean protein, wheat albumin, egg albumin, zein & lactose, and no casein & xylose, no description regarding any other browning reaction products is being disclosed in the specification. In addition, the invention only provides the description of *Helicobacter pylori* adhesion assay and eradication test, no description regarding treating any other *Helicobacter pylori* associated disease, such as stomach cancer, is being disclosed in the specification. Accordingly, in the absence of sufficient recitation of any browning reaction for treating any *Helicobacter pylori* associated disease, the specification does not provide adequate written description of the claimed invention.

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Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the ‘written description’ inquiry, whatever is now claimed. The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is now is claimed.” (See Vas-Cath at page 1116). As discussed above, the skilled artisan cannot envision the detailed compound being claimed, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the compound. Adequate written description requires more than a mere statement of the total amount of the plant material being used. See *Fiers v. Revel*, 25USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18USPQ2d 1016.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F. 2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does “little more than outline [goals] appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.”) Accordingly, it is deemed that the specification fails to provide adequate written description for the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed had possession of the claimed invention.

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Claims 19-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for *Helicobacter pylori* adhesion assay and eradication test, does not reasonably provide enablement for treating any *Helicobacter pylori* associated disease, such as stomach cancer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

As evidenced by Kamb (Kamb, Nature Reviews, 4: 161-165, 2005), cancer is among the most challenging of the therapeutic areas. The use of drugs that kill cells and which are consequently often toxic; and the rates of failure in expensive phase III trials that eclipse many other disease areas. The poor performance of most investigational cancer drugs implies that the standard preclinical disease models are faulty. As mentioned above, the invention only provides the description *Helicobacter pylori* adhesion assay and eradication test, and no description regarding the treatment of any *Helicobacter pylori* associated disease, such as stomach cancer is being disclosed in the specification. It is the opinion of the Examiner, in light of the grave unpredictability in the art with regard to treat cancer, for instance, that Applicant is not enabled for treating any *Helicobacter pylori* associated disease as instantly claimed. Considering this evidence, the skilled artisan, lacking information with regard to treat cancer, would necessarily need to perform tedious trial and error protocols without expectation of success in order to provide for the specific activity as claimed.

In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), held that

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"Inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since such improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; *however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112*; that paragraph requires that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved." (Emphasis added)

Due to the large quantity of experimentation necessary to generate the infinite number of variants/fragments recited in the claims and possibly screen same for activity and the lack of guidance/direction provided in the instant specification, this is merely an invitation to the skilled artisan to use the current invention as a starting point for further experimentation. Thus, undue experimentation would be required for a skilled artisan to make and/or use the claimed invention commensurate in scope with the claims.

Claim Rejections –35 USC § 112, 2nd

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 19-24 recite “a method for treating disease associated with *Helicobacter pylori*”, and it is not clear what disease(s) Applicant is referring to, and the metes and bounds of the claims are uncertain.

Claim Rejections –35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15-18, and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al (US 6,329,002), in view of Kim et al (US 6,627,238).

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Kim et al (US 6,329,002) teach a method of preventing and/or treating disorders associated with infection by *Helicobacter pylori* with nutritional food in combination with an active strain of a living microorganism in an amount effective to inhibit or prevent the growth of *H. pylori* in a human stomach (claim 8). The living organism being of lactic acid origin is selected from the group consisting yogurt, buttermilk, cream cheese, and ice cream (claim 12). Therefore, any one who eats a toast bagel (nutritional food) with cream cheese (lactic acid origin, contains living microorganism) (animal proteins derived from milk) reads on treating disorders associated with infection by *Helicobacter pylori*. Further more, as evidenced by Wikipedia online, all major dietary carbohydrates contain glucose, and D-glucose and L-glucose are the two isoforms of glucose, thus a bagel would contain sugar D-glucose. Kim further teaches a method for prevention and/or treatment of gastritis, duodenal and gastric ulcers caused by infection from *Helicobacter pylori* (see Abstract).

Kim et al (US 6,329,002) do not teach the claimed amount of browning reaction product.

Kim et al (US 6,627,238) teaches that browning reaction that contains sugars such as glucose, fructose, galactose, lactose, and free amino groups from proteins of microorganisms (buttermilk, cream cheese) (col 2, lines 4-10) occurs in foods heated by microwave, food containing a dough crust heated in a conventional oven, and food to be baked (col 1, lines 30-35; col 2, lines 50-55) [which reads on any one who eats a toast bagel (nutritional food) with cream cheese (lactic acid origin, contains living microorganism) (animal proteins derived from milk)].

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Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to consume the browning reaction product, a toasted bagel, in the invention of Kim et al (US 6,627,238), as a nutritional food, to combine with an active strain of a living microorganism, cheese, in the invention of Kim et al (US 6,329,002), to prevent and/or treat disorders associated with infection by *Helicobacter pylori*. Since the bagel/cheese consumption varies according to people's appetite, age, and weight, the amount of browning reaction product as claimed is a result-effective adjustment in conventional working parameter, which is deemed merely a matter of judicious selection and routine optimization that is well within the purview of the skilled artisan.

Claims 15-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al (US 6,329,002), in view of Kim et al (US 6,627,238), and further in view of Kodama et al (US 2001/0044120).

Kim et al (US 6,329,002) teach a method of preventing and/or treating disorders associated with infection by *Helicobacter pylori* with nutritional food in combination with an active strain of a living microorganism in an amount effective to inhibit or prevent the growth of *H. pylori* in a human stomach (claim 8). The living organism being of lactic acid origin is selected from the group consisting yogurt, buttermilk, cream cheese, and ice cream (claim 12). Therefore, any one who eats a toast bagel (nutritional food) with cream cheese (lactic acid origin, contains living microorganism) (animal proteins derived from milk) reads on treating disorders

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associated with infection by *Helicobacter pylori*. Further more, as evidenced by Wikipedia online, all major dietary carbohydrates contain glucose, and D-glucose and L-glucose are the two isoforms of glucose, thus a bagel would contain sugar D-glucose. Kim further teaches a method for prevention and/or treatment of gastritis, duodenal and gastric ulcers caused by infection from *Helicobacter pylori* (see Abstract).

Kim et al (US 6,329,002) do not teach the claimed amount of browning reaction product, or an inhibitor of gastric acid secretion to inhibit *Helicobacter pylori*.

Kim et al (US 6,627,238) teaches that browning reaction that contains sugars such as glucose, fructose, galactose, lactose, and free amino groups from proteins of microorganisms (buttermilk, cream cheese) (col 2, lines 4-10) occurs in foods heated by microwave, food containing a dough crust heated in a conventional oven, and food to be baked (col 1, lines 30-35; col 2, lines 50-55) [which reads on any one who eats a toast bagel (nutritional food) with cream cheese (lactic acid origin, contains living microorganism) (animal proteins derived from milk)].

Kodama et al teach inhibiting *Helicobacter pylori* with glycoprotein isolated from milk, dairy products, and meat products, and an inhibitor of gastric acid secretion (see Title, Abstract, [0034, 0044]. Kodama et al also teach that the combination of the glycoprotein and the inhibitor of gastric acid secretion is more effective in eliminating *Helicobacter pylori* [0044].

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to consume the browning reaction product, a toasted bagel, in the invention of Kim et al (US 6,627,238), as a nutritional food, to combine with an active strain of a living microorganism, cheese, in the invention of Kim et al (US 6,329,002), to prevent and/or treat disorders associated with infection by *Helicobacter pylori*. Since the bagel/cheese consumption varies according to people's appetite, age, and weight, the amount of browning reaction product as claimed is a result-effective adjustment in conventional working parameter, which is deemed merely a matter of judicious selection and routine optimization that is well within the purview of the skilled artisan.

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use an inhibitor of gastric acid secretion from Kodama et al since Kodama et al teach that the combination of the glycoprotein which contained in the milk and dairy products, with the inhibitor of gastric acid secretion is more effective in eliminating *Helicobacter pylori*. Since both Kim et al (US 6,329,002) and Kodama et al yielded beneficial results in inhibiting *Helicobacter pylori*, one of ordinary skill in the art would have been motivated to make the modifications.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Answer to Applicant's Argument

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Applicant argues that Kim et al (238) do not teach 0.5% by mass of a browning product, and the Maillard reaction mixture in Shimzaki et al is prepared by heating sugar and specific amino acid (page 4, 6th–8th paragraphs). Applicant's arguments have been fully considered and are persuasive. The 102 rejection has been withdrawn.

Applicant argues that there is no reason to combine the cited references when they do not teach that it is the product of a browning reaction that inhibits *Helicobacter pylori* infection (page 5, 3rd paragraph). The cited references were combined for the reasons indicated above.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Qiuwen Mi

/Patricia Leith/

Patricia Leith

Primary Examiner

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